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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL J. PRECOPIO

Appeal 2009-009634
Application 10/519,372
Technology Center 1600

Decided: March 4, 2010

Before ERIC GRIMES, FRANCISCO C. PRATS, and STEPHEN WALSH,
Administrative Patent Judges.

WALSH, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a method for the topical treatment of ectoparasites, e.g., lice. The Patent Examiner rejected some claims as anticipated and all the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

“This invention relates to methods for treating ectoparasite infestations on mammalian bodies, particularly lice infestations in humans.” (Spec. 1:24-25.) Claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, 33-36 and 45-63, which are all the pending claims, are on appeal.

Claims 1 and 45 are representative. Claim 1 defines a method for treating ectoparasites. Claim 45 defines a method for treating lice. The method in claim 45 differs from the method in claim 1 by replacing nearly all references to the target “ectoparasites” and “eggs” with “lice” and “nits,” respectively. Claims 1 and 45, using brackets to show where claim 45 differs, read as follows:

1 [45]. A method for the topical treatment of ectoparasites [lice], their nymphs, and their eggs [nits], on mammalian skin and hair comprising the steps of:

A) applying a water soluble or water-dispersible, substantially air impermeable, pharmacologically acceptable barrier composition containing at least one pesticidally-active monohydric aralkyl alcohol to areas of mammal skin and hair infected with ectoparasites [lice] wherein

a) the composition contains a quantity in the range of from about 1 to about 50% by weight of the at least one monohydric aralkyl alcohol sufficient to provide pesticidal activity against the ectoparasites, their nymphs, and their eggs,

b) the composition is formulated so that when applied to the ectoparasites [lice], the composition prevents them from obtaining air through their breathing apparatuses,

c) the composition is applied to the infected areas in a quantity sufficient to completely saturate both the hair and the skin in the infected areas,

d) the composition can be readily washed out of the infected areas by rinsing with water, and

e) the composition is free from any effective pesticidally active

compounds other than the at least one pesticidally-active monohydric aralkyl alcohol, and

B) leaving the composition in contact with the skin and hair in the infected area until at least most of the ectoparasites [lice], nymphs and eggs [nits] have been killed; and

C) removing the composition, the dead ectoparasites [lice], and dead nymphs from the skin and hair with water or other aqueous based liquid.

The Examiner relied on the following evidence:

| | | |
|---------------|-------------------|---------------|
| Lover et al. | US 4,368,207 | Jan. 11, 1983 |
| Cardin et al. | US 5,288,483 | Feb. 22, 1994 |
| Pearlman | US 6,303,581 | Oct. 16, 2001 |
| Precopio | US 6,793,931 | Sep. 21, 2004 |
| Bessette | US 6,974,584 | Dec. 13, 2005 |
| Precopio | US 7,292,342 | Nov. 13, 2007 |
| Gans et al | US 2003/0040504 | Feb. 27, 2003 |
| Precopio | US SN# 10/382,188 | Mar. 04, 2003 |

The Examiner rejected the claims as follows:

- claims 45-48, 50-53 and 55-63 under 35 U.S.C. § 102(b) as anticipated by Gans;¹
- claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, 33-36 and 45-63 under 35 U.S.C. § 103(a) as unpatentable over the combined teachings of Lover, Bessette, Cardin and Pearlman;
- claims 1, 3-5, 8, 9, 13, 18, 20 and 22-26 on the ground of nonstatutory obviousness-type double patenting over claims 28, 29 and 31-38 of Precopio '931;

¹ The Final Rejection included claim 54 in this group. (Fin. Rej. 2; App. Br. 15.) The Examiner's Answer does not (Ans. 4); we conclude the Examiner withdrew the anticipation rejection of claim 54.

- claims 1, 3-6, 8, 9, 13, 15, 16, 18, 20, 22-26 and 33 provisionally on the ground nonstatutory obviousness-type double patenting over pending claims 33, 35-38, 44-46, 49-51, 65-67 and 69-81 of Precopio '188; and
- claims 1, 3-5, 8, 9, 11, 13, 15, 16, 18 and 20 on the ground of nonstatutory obviousness-type double patenting over claims 1-3, 5-13, 15 and 16 of Precopio '342.

ANTICIPATION

The Issue

The Examiner's position is that Gans described the claimed method using benzyl alcohol as the sole active ingredient at a concentration of from 0.5-20%, applied in gel or shampoo, left on for up to 20 minutes and rinsed off with water. (Fin. Rej. 2.) "Although GANS provide[d] no explicit instruction to completely saturate the hair & skin of affected areas, the intent to achieve 100% kill with 1 application is clearly the impetus to sufficiently cover [the hair and skin]." (Ans. 5.)

Appellant contends that Gans paragraph [0021] disclosed benzyl alcohol as a second active ingredient; that Gans did not disclose air-impermeable compositions; that Gans paragraph [0014] required four active ingredients to kill eggs and lice; that the Examiner cited Gans Examples VI and XII as air impermeable compositions but that those examples used active ingredients in addition to benzyl alcohol; and that there is no basis for the Examiner's assumption that Gans disclosed air impermeable compositions. (App. Br. 16-17.) Appellant argues that in contrast to the about 20 minute time Gans disclosed for benzyl alcohol compositions to kill

ectoparasites, only 2-10 minutes are needed for suffocating ectoparasites with Appellant's method. (*Id.* at 17.)

The issue with respect to this rejection is whether the evidence supports the Examiner's finding that Gans described the method defined in claim 45.

Findings of Fact

1. Gans described compositions and methods for killing mammalian ectoparasites and eggs. (Gans, Abstract.)
2. Gans described a preferred composition in which benzyl alcohol was the sole active ingredient, in an amount "from about 0.50% w/w to about 20% w/w," and in additional preferred embodiments "from about 3% w/w to about 6% w/w, preferably 4.5% w/w." (Gans, 10:[0107]-[0108].)
3. Gans taught topical application to the hair and scalp to treat head lice. (Gans, 10:[0110].)
4. Gans taught carriers including a gel, a thickening agent such as polyethylene glycol, and others. (*Id.*)
5. "A preferred embodiment of the [Gans] invention comprises applying a composition to mammalian ectoparasites on mammals for a short time (for example, without limitation, about 5 to about 30 minutes), and then rinsing." (Gans, 11:[0113].)
6. "In preferred embodiments, the compositions and methods disclosed herein are used on humans to control human ectoparasites and in particular, human lice." (Gans, 4:[0051].)

7. Gans disclosed using a single active ingredient in combination with an adjuvant:

An adjuvant is an ingredient that assists in the killing event in some way. Examples of adjuvants include, for example, certain essential oils . . . that do not substantially kill ectoparasites on their own but which in combination with an active ingredient, assists the killing effect of the active ingredient, such as, for example, by maintaining the active ingredient in place on the area to be treated.

(Gans, 9:[0099].)

8. Appellant's Specification discloses that the compositions employed in the methods of the invention kill the ectoparasites "by a combination of suffocation and pesticidal, e.g, pediculicidal, activity of the aralkyl alcohols where the compositions are air-impermeable and these are the only mechanisms of action [T]he ectoparasite eggs are also killed by the insecticidal activity of the aralkyl alcohols." (Spec. 9:6-10.)
9. "By substantially air-impermeable is meant that the composition does not contain sufficient air nor does it permit air to penetrate the composition in a quantity that would prevent the composition from suffocating the ectoparasites." (*Id.* at 8:8-10.)

Principles of Law

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. Anticipation is an issue of fact, and the question whether a claim limitation is inherent in a prior art reference is a factual issue.

In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (citations omitted).

The test for anticipation “is not an ‘ipsissimis verbis’ test.” *In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990). “An anticipation reference, however, need not duplicate word for word what is in the claims. Anticipation can occur when a claimed limitation is ‘inherent’ or otherwise implicit in the relevant reference.” *Standard Havens Prods., Inc. v. Gecor Indus., Inc.*, 953 F.2d 1360, 1369 (Fed.Cir.1991). “[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” *In re Preda*, 401 F.2d 825, 826-27 (CCPA 1968) (affirming anticipation finding of implicit fact).

“The anticipation analysis asks solely whether the prior art reference discloses and enables the claimed invention, and not how the prior art characterizes that disclosure or whether alternatives are also disclosed.” *Hewlett-Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1324 n.6 (Fed. Cir. 2003), quoted in *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005) (affirming anticipation where the prior art’s “disclosed range of concentration also does not exactly correspond to [the] claimed range,” 432 F.3d at 1377).

Analysis

Claim 45

We agree with the Examiner that Gans described the invention defined in Appellant’s claim 45. Appellant’s arguments about Gans teaching multiple active ingredients are unpersuasive because Gans explicitly described an embodiment in which benzyl alcohol was the only active ingredient (FF2). Moreover, the Examiner emphasized the clarity of

Gans' disclosure on this point by pointing to Gans' claim 12, which explicitly recited benzyl alcohol as the sole active ingredient. (Ans. 4.)

According to Appellant, Gans' composition containing only benzyl alcohol as the sole active ingredient could not have been air impermeable because Gans ¶[0107] "gives a time of about 20 minutes . . . to kill ectoparasites." (App. Br. 17.) The evidence does not support Appellant's reading that Gans required 20 minutes. Gans ¶[0107] states: "Benzyl alcohol, for example, is effective at killing ectoparasites within about 20 minutes, or preferably less time, of the initial application" (emphasis added). Thus, Gans did not teach that 20 minutes was required. The Examiner also cites Gans' disclosure of a preferred embodiment applying the composition "for a short time (for example, without limitation, about 5 to about 30 minutes), and then rinsing. The ectoparasites are killed or stunned and the live and dead ectoparasites and their eggs are effectively removed from the mammal." (Gans 11:[0113].)

Appellant contends that, in contrast to Gans, "time frames of only 2-10 minutes are needed for suffocating the ectoparasites" in the claimed method, to kill rates of "greater than 99%," "94.9%," and "93.1%." (App. Br. at 17-18, *citing* Spec. at 5, and Examples 15 and 17.) Appellant's Specification discloses:

contact time is somewhat dependent on the particular ectoparasite being treated, but it has now been discovered that in general the contact time can be for a period of at least 2 minutes, preferably at least 3 minutes, and more preferably at least 5 minutes. Periods of from 2 to 10 minutes can be used, preferably from 3 to 10 minutes, e.g. from 3 to 8 or 9 minutes. It has now been found that contact times of greater than 9 or 10 minutes are unnecessary and do not provide any additional benefits, particularly where the composition is

air-impermeable, although of course longer contact times can be used if desired.

(Spec. at 5:18-6:2.) The Specification does not persuade us that claim 45 can be distinguished from Gans' explicit disclosure of an about 5 minute treatment time. Claim 45 does not recite time in minutes; instead, its temporal limitation is functional: "until at least most of the ectoparasites, nymphs and eggs have been killed." The Examiner's evidence was sufficient to shift the burden to Appellant to show that Gans' method did not perform that function. *See Schrieber*, 128 F.3d at 1478. Appellant argues that Example 15 shows "a kill rate greater than 99% was achieved in 10 minutes," *citing* Spec. p. 26, ll. 18-20. (App. Br. 17.) However, the text makes it clear that the greater than 99% kill rate was determined "[a]t the Day 8 post treatment," (Spec. 26:18), i.e., after two 10-minute treatments separated by a week. Cf. Spec. 26:3-4 ("At the day 8 pre-treatment evaluation, subjects in both the 10-minute and 30-minute application treatment groups had lice and nits present."). We find that Example 15 does not show that claim 45 is distinguished from Gans' about 5 minute method. Example 17 is similarly unpersuasive because it discloses a 10 minute in vitro anti-nit procedure, which is not comparable to Gans' about 5 minute in vivo method.

Appellant disputes the Examiner's finding that Gans disclosed applying the composition to the infected areas in "a quantity sufficient to completely saturate both the hair and the skin in the infected areas," as required by claim 45(A)(c). (App. Br. 18.) We agree that Gans did not explicitly use those terms. However, we agree with the Examiner that in context, that is how those in this art would understand Gans' disclosure.

(See Ans. 5.) The Examiner cited, e.g., Gans at 10:[0110], which disclosed topical treatment of the hair and scalp, and formulating the active ingredient as “a cleanser (preferably, a shampoo).” (*Id.*) Gans did not teach applying shampoo to only portions of the hair and scalp, but instead taught applying it to hair and scalp. Appellant has not provided a reasonable basis to find that a skilled artisan would understand Gans meant to apply the shampoo only partly. We think the Examiner correctly explained what Gans’ disclosure meant to those in this art. See *Preda*, 401 F.2d at 826-27.

Appellant refers to the Declaration under 37 CFR 1.132 dated June 4, 2007 (App. Br. 18.), but the Declaration does not address whether Gans disclosed applying a saturating quantity. The Declaration compares two studies, or treatment protocols. In STUDY 1, a composition was applied to the hair and skin of the subjects and then rinsed off, resulting in a kill rate of 89%. (Decl. 2-3.) In STUDY 2, “the quantity of the composition was adjusted for each subject so that complete saturation of the entire length of each subjects hair was obtained,” resulting in a kill rate of greater than 99%. (Decl. 3.) According to the Declaration, “[t]he results obtained in Study 1 were found to have resulted from incomplete saturation of the entire length of the long hairs in the subject population of that study.” (*Id.*) According to the Declaration, the finding “that the entire length of the subject’s hair must be completely saturated with the compositions of the invention to obtain very high treatment success and kill rates, was unexpected and unobvious.” (*Id.*) The Declaration does not address whether Gans did or did not implicitly disclose using saturating quantities, nor does it take a position on how a person of skill in this art would have understood Gans.

Claim 48

Appellant argues that Gans' disclosure of repeated administrations in ¶[0084] is "essentially meaningless with respect to any particular composition having the ability to 'kill human ectoparasite eggs.'" (App. Br. 19.) Appellant bases the argument on Gans' statement "it is believed that these compositions and/or methods will also kill human ectoparasite eggs." (*Id.*) Gans expressly disclosed killing mammalian ectoparasite eggs, and that human head lice were targets. *See, e.g.*, Gans 1:[0012], claim 12 and claim 50. Appellant's emphasis on the "it is believed" phrase is unpersuasive when Gans' disclosure is considered as a whole.

Claims 55-59

Appellant argues that Gans did not disclose the recited ranges for benzyl alcohol (App. Br. 19.) We disagree. The ranges recited in these claims are 1-20%, 2-20%, 2-9%, 3-7%, and 4-6%, respectively. Gans taught benzyl alcohol in an amount from about 0.50% to about 20%, and in preferred embodiments "from about 3% w/w to about 6% w/w, preferably 4.5% w/w". (FF2.) Every percentage that Appellant recites for use in the method includes the 4.5% species expressly disclosed by Gans. Gans therefore anticipates the recited ranges. *See Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985) ("[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if *one* of them is in the prior art.").

Claim 62

Appellant argues that Gans did not disclose contact for "at least" about 2 minutes; that Gans did not disclose treating head lice; and that Gans did not disclose treating the skin and hair of a human being. (App. Br. 19.)

We disagree. Gans' 5 minute treatment was "at least" about 2 minutes (FF5); Gans taught treating head lice by applying the composition to hair and scalp (FF3); and Gans taught treating human beings (FF6).

Claims 46, 47, 50-53, 60, 61 and 63 have not been argued separately and therefore fall with representative claim 45. 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS

The Issue

The Examiner's position is that Lover taught the use of phenyl ethyl and benzyl alcohols as single active agents at concentrations of 10-40% in gels or shampoos to kill lice and their eggs, but that Lover did not discuss suffocation, rinsing or saturating. (Ans. 7.) The Examiner found that Bessette disclosed benzyl alcohol in gel and shampoo carriers to control human head and body lice, resulting in 100% mortality. (*Id.*) The Examiner found that Bessette's "application thus must include thorough saturation of hair and scalp, since it must be applied in an amount sufficient to effect the desired action." (*Id.*) According to the Examiner, Cardin taught using compounds within Appellant's formula I, including phenyl alkanols, phenyl propanol and phenyl ethyl alcohol, in lotions worked into the hair and scalp, left on for 6-10 minutes and then rinsed off. (*Id.* at 8.) The Examiner found that Cardin's teaching of working the compositions into the scalp and hair met the "sufficient to saturate" requirement of the claims. (Fin. Rej. 3.) Caardin also taught formulating the compositions with Appellant's claimed film formers, surfactants, and gelling or thickening agents. (Ans. 8.) The Examiner found that Pearlman treated human ectoparasites with barrier compositions that suffocate lice. (*Id.*) Pearlman taught using surfactants

and adjuvants, thickeners and gums. (*Id.* at 9.) Pearlman used phenyl alkanols as solvents. (*Id.*)

The Examiner concluded that it would have been obvious to use the compositions and methods disclosed in Lover, Bessette, Cardin and Pearlman to increase pesticidal efficacy without irritation or side effects, to increase stability, dispersibility, and reduce toxicity to the person infected. (*Id.*) According to the Examiner, “the artisan would readily select the instant aralkyl alcohol, as benzyl or phenyl ethyl alcohol shown effective by Lover [and] Bessette to provide a high rate of kill of both lice [and] their ova when applied to hair and scalp at 1-20% of a carrier composition of shampoo, film or gel, to permit retention for a 20 minute period before being washed off, as shown by Cardin also using the instant formula I aralkyl alcohol to kill lice.” (*Id.*) Whether Cardin’s phenyl ethanol or Lover or Bessette’s benzyl alcohol was used, Pearlman taught that lice treatment consisted of thorough wetting of hair and scalp, leaving in place for a few minutes, rinsing off, and repeating if needed. (*Id.*)

Appellant contends that Lover’s results show that benzyl alcohol was not effective at killing lice, and that Lover teaches away from using either benzyl alcohol or phenyl ethanol. (App. Br. 20-21 and 24.) Appellant contends that Bessette disclosed that only benzyl alcohol in combination with pyrethrins gave a “very good kill.” (*Id.* at 27.) Appellant contends that Cardin disclosed alkanols only as synergizers for pediculicide ammonium or amine compounds, i.e., not as the claimed sole active agent. (*Id.* at 29.) According to Appellant, Cardin’s disclosure of working the composition into the scalp is therefore not relevant to the claimed method. (*Id.*) Further, according to Appellant, the Declaration “shows the unexpected criticality of

making certain even the longest strands of hair are completely saturated with the present compositions, which is clearly not disclosed by Cardin.” (*Id.* at 30.) Appellant contends that Pearlman “is directed to drible pediculostatic agents that elicit an ‘immersion reflex’ in lice to immobilize them,” does not disclose monohydric aralkyl alcohols, and “contain[s] no disclosures relevant to the presently claimed invention.” (*Id.* at 32.) According to Appellant, the rejection combines the references without a teaching or suggestion to do so in the references, and is “a hindsight rejection using the present invention as a template.” (*Id.*) Further, Appellant contends that the rejection does not account for all the features of the claims. (*Id.* at 34-35.)

The issues with respect to this rejection are:

whether the explanation of the rejection accounted for all the limitations of the claims; and

whether the Examiner provided a properly reasoned basis for combining the teachings of the references.

Findings of Fact

Lover

10. Lover disclosed that phenyl ethyl alcohol and benzyl alcohol kill ectoparasites and their eggs, including lice and mites, as evidenced by the results of two minute immersion tests. (Lover, cols. 3 and 4.)
11. Lover’s Table I shows lice killing ratings (i.e., percent mortality) for various solutions including benzyl alcohol and 2-phenylethanol. 100% benzyl alcohol had a rating of 90, 25% benzyl alcohol had a rating of 0, and 15% benzyl alcohol in 25% isopropanol had a rating

- of 5. 100% 2-phenylethanol had a rating of 100, and 15% 2-phenylethanol in 25% isopropanol had a rating of 80. (*Id.* at col. 3.)
12. We find that isopropanol is an active lice killing agent because Lover's Table I disclosed that 100% isopropanol had a kill rating of 65. (*Id.*)
13. Lover's Table II shows lice egg killing ratings (i.e., percent mortality) for various solutions including benzyl alcohol and 2-phenylethanol. 100% benzyl alcohol had a rating of 100, 25% benzyl alcohol had a rating of 100, and 15% benzyl alcohol in 25% isopropanol had a rating of 29. 100% 2-phenylethanol had a rating of 100, 25% 2-phenylethanol had a rating of 100, and 15% 2-phenylethanol in 25% isopropanol had a rating of 34. (*Id.* at col. 4.)
14. Lover's Table III shows mite killing ratings for various alcohol solutions. 100% benzyl alcohol and 100% 2-phenylethanol had the same rating: 100. (*Id.* at col. 4.)
15. Lover taught that the minimum concentration required for an effective toxic amount varied depending on the alcohol and carrier used, so that "in one case a 10% concentration may suffice, while in other cases, concentrations as high as 30 to 40% may be required to obtain an effective toxic dose." (*Id.* at col. 2, ll. 39-48.)
16. Lover taught end use formulations including gel and shampoo. (*Id.* at col. 5.)

Bessette

17. Bessette disclosed using a plant essential oil to control the human body louse. (Bessette, col. 2, ll. 50-57.)

18. Bessette taught that benzyl alcohol was a plant essential oil that could be used. (*Id.* at col. 3, ll. 22-23.)
19. According to Bessette, “[u]se of pesticidal compositions of the present invention generally results in 100% mortality on contact . . . employed as pesticidal agents in uses as . . . shampoos, hair gels, body cremes, lotions, and other on-skin application for the treatment of head lice, body lice, and pubic lice.” (*Id.* at col. 3, ll. 61-67.)
20. Bessette disclosed applying the compound “in an amount sufficient to effect the desired action.” (*Id.* at col. 6, ll. 32-37.)
21. The Examiner found that Bessette’s application “must include thorough saturation of hair and scalp, since it must be applied in an amount sufficient to effect the desired action.” (Ans. 7.)
22. Bessette taught that in general “the effective dosage . . . is of the order of 0.001 to 5.0% based on total weight of the formulation, though under some circumstances the effective concentrations will be as little as 0.0001% or as much as 20%, on the same basis.” (*Id.* at col. 6, ll. 35-52.)

Cardin

23. Cardin taught anti-lice compositions comprising “quaternary ammonium salts, fatty amines, and mixtures thereof with low levels of specific alkanols.” (Cardin, col. 1, ll. 10-12.)
24. Cardin’s alkanols included phenyl C₂-C₆ alkanols such as phenyl ethanol. (*Id.* at col. 3, ll. 33-47.)
25. Cardin taught using the alkanols at about 0.5% to about 5%. (*Id.* at col. 5, l. 64 – col. 6, l. 5.)

26. Cardin taught using thickening agents, gums, and polymers. (*Id.* at col. 12, ll. 54-68.)
27. Cardin taught applying the composition to wet hair, “(b) working said composition through the hair and scalp; (c) leaving the composition on the hair and scalp for about 6-10 minutes; and (d) rinsing the composition from the hair.” (*Id.* at col. 12, ll. 22-33.)

Pearlman

28. Pearlman disclosed a method of treating lice infestations by applying “an effective amount of a driable pediculostatic agent for a time sufficient to immobilize the lice, drying the agent onto the application site and removing the dried agent, thereby removing the lice and nits.” (Pearlman, Abstract.)
29. Pearlman taught:

A pediculostatic agent is one that elicits the “immersion reflex” in lice. . . . During submersion, the spiracles and tracheoles, through which lice breathe, become blocked by water. As the lice become anoxic, they rapidly switch to a state of profound suspended animation, decreasing their need for oxygen If the reflex continues too long, however, the lice eventually run completely out of oxygen and die from anoxia.

(*Id.* at col. 5, ll. 1-16.)
30. Pearlman’s “driable pediculostatic agent is one that triggers the immersion reflex when wet, and that maintains the lice in the immersion reflex when thereafter dried in situ.” (*Id.* at col. 5, ll. 18-20.)
31. Pearlman disclosed that “[f]or most driable pediculostatic agents, at least some of the lice can be killed by leaving the dried agent on the lice and hair for at least about 8 hours.” (*Id.* at col. 8, ll. 8-10.)

32. Pearlman taught using surfactants (*id.* at col. 11, ll. 51-57) and solvents to hasten the drying time such as phenyl C2-C6 alkanols (*id.* at col. 13, ll. 28-32).
33. Pearlman taught using thickeners. (*Id.* at col. 13, ll. 56-60.)

Principles of Law

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). “[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” *Id.* at 417. The obviousness “analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418.

“In considering [prior art] disclosures, it is proper to take into account not only specific teachings of the references but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” *In re Hoeschele*, 406 F.2d 1403, 1406-07 (CCPA 1969) (affirming findings and conclusion of obviousness) (citations omitted). Each prior art reference “must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole.” *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (citation omitted). “Obviousness does not require absolute predictability of success. . . . [A]ll that is required is a reasonable

expectation of success.” *In re O’Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988).

“[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art.” *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991) (“Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention.”).

Analysis

Appellant argues that Lover does not teach or suggest the monohydric aralkyl concentration range of the claims. (App. Br. 20-22.) The Examiner found that Lover tested alcohols and the results showed that compositions containing 10-40% alcohol were pesticidally active. (Ans. 7.) However, Lover did not show that a composition of a monohydric aralkyl alcohol, as the only active compound, was active in killing both ectoparasites and their eggs, in that range. (FF11-14.) While we agree that Lover provided general guidance that effective concentrations would vary according to the alcohol chosen, the tabular data for benzyl alcohol or phenylethanol (FF11-14), does not show that either would be effective in the general 10-40% range (FF15). The evidence is insufficient to support a finding that Lover disclosed effective monohydric aralkyl formulations in the claimed 1-50% range.

The Examiner found Bessette disclosed effective benzyl alcohol formulations of 0.001-5% and up to 20% (Ans. 7.) The evidence supports that finding. (FF22.) Appellant argues that the only benzyl alcohol formulation Bessette tested (contact toxicity) that showed a “kill rating” is excluded by Appellant’s claims because it also contained pyrethrins. (App.

Br. 27.) This argument is unpersuasive because Bessette explicitly taught formulating up to 20% of an active agent alone, such as benzyl alcohol, to kill ectoparasites, including lice. We conclude that Bessette's disclosure supplemented Lover's disclosure, and rendered the claimed range obvious at the time of Appellant's invention.

The Examiner found that Cardin disclosed licicidal formulations of phenyl alkanols of Appellant's formula I, free of conventional pesticides. (Ans. 8.) We agree with Appellant that the evidence does not support that finding because Cardin's formulations included quaternary ammonium salts (FF23), which had pediculicidal activity. However, we find Cardin pertinent to the subject matter of Lover, Bessette and Pearlman, and that Cardin is analogous art. We agree with the Examiner that Cardin's teachings of film formers, surfactants, gelling and thickening agents, gums and polymers, and methods of working the licicidal composition into the hair would have been suggestive to the ordinary artisan.

The Examiner found that "[r]egardless of the particular agent used . . . treatment for lice is shown by Pearlman to consist of application to the hair & scalp of a composition by thorough wetting of hair & scalp, leaving in place for a few minutes, rinsing off & repeating if needed." (Ans. 9.) Appellant argues that Pearlman contains "no disclosures relevant to the presently claimed invention," and cites seven asserted elements of the claims. (App. Br. 32.) We agree with the Examiner that Pearlman is analogous art. However, the evidence does not support the Examiner's finding that Pearlman taught leaving the composition in place for only a few minutes (the "short time" in Appellant's list of items). (FF31.) Although "short time" is not a feature of the independent claims, pediculicide contact

periods up to 10 minutes recited in dependent claims were known in the art (e.g. FF27) and would have been obvious.

We also agree with the Examiner that Pearlman's explanation of suffocating compositions shows that suffocation would have been the expected result of the known benzyl alcohol formulations and treatment methods suggested by Bessette in combination with the other references. See FF29.

Appellant argues that "the Examiner does not explain why the disclosed processes in the prior art would inherently (necessarily) yield the same product used in the present method claims." (App. Br. 33.) However, Bessette taught using benzyl alcohol alone, and the evidence supports the Examiner's view that Appellant's claims combine the use of known components for their known properties. Combining the known formulations and known methods was within the level of skill in the art, and Appellant has not shown that the ordinary artisan would not have had a reasonable expectation of success in doing so.

Appellant argues that data shows the products used in the claimed method exhibit properties "which are not exhibited by those prepared in accordance with any process disclosed in the references." (App. Br. 33-34, referencing Spec. Examples 1-17.) None of the examples show comparative data against the closest prior art. None of the examples show that air impermeability or suffocating ability could be a property of Appellant's 1-50% benzyl alcohol formulation but not a property of Bessette's up to 20% benzyl alcohol formulation.

Claims 3-9, 11, 13, 15, 16, 18, 20-26, 33-36 and 45-63 have not been separately argued and therefore fall with representative claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

NONSTATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING

Principles of Law

The analysis employed in an obviousness-type double patenting rejection is similar to the analysis used in a 35 U.S.C. § 103 obviousness determination. *In re Braat*, 937 F.2d 589, 592-93 (Fed. Cir. 1991). A generic invention is anticipated by a species covered by an earlier claim; absent a terminal disclaimer, the species claims preclude issuance of a generic claim. *In re Goodman*, 11 F.3d 1046, 1053 (Fed. Cir. 1993).

Issue

The Examiner concluded that the claims on appeal are not patentably distinct from certain patented or copending claims, and required Appellant to file terminal disclaimers limiting any patent term for the appealed claims by the terms of the two cited patents and the cited application.

Analysis Involving The '931 and '342 Patent Claims

Appellant contends that the rejections over the '931 patent and the '342 patent should be reversed because the patented claims do not contain these limitations of the claims on appeal, and nothing in the patented claims renders these limitations obvious:

1) effectiveness against nymphs and eggs as well as the ectoparasites themselves;

- 2) the requirement of complete saturation of the hair and skin;
- 3) leaving the composition in contact with the infected skin and hair until most of the nymphs and eggs have been killed; and
- 4) topical treatment of ectoparasites, not just lice. (App. Br. 37-38; 39-40.) We address these points in turn.

1) The claims on appeal define a method “for the topical treatment of ectoparasites, their nymphs, and their eggs” (claim 1), or “for the topical treatment of lice, their nymphs, and their nits” (claim 45). Claim 28 in the ‘931 patent defines a method “for the topical treatment of lice.” Claim 1 in the ‘342 patent defines a method “for the topical treatment of lice infestations.” The generic aspect of the appealed claims is anticipated by the species “lice” in the issued claims, and the requirements for terminal disclaimer were proper in this regard. *See Goodman*, 11 F.3d at 1053. Appellant’s first point is therefore unpersuasive.

2) The claims on appeal define a method “wherein . . . c) the composition is applied to the infected areas in a quantity sufficient to completely saturate both the hair and the skin in the infected areas.” Claim 28 in the ‘931 patent defines a method comprising “applying [a composition] to the skin and hair containing lice.” Claim 1 in the ‘342 patent defines a method comprising “applying [a composition] to the skin and hair containing lice.” While neither set of patent claims recites “complete saturation” of hair and skin, we construe those claims to mean what they say: apply the composition to the hair and the skin. We agree with the Examiner that a person of ordinary skill would understand that to mean covering the hair and skin completely. It is permissible to take into account the inferences a person of ordinary skill in the art would employ. *See KSR*,

550 U.S. at 418; *Hoeschele*, 406 F.2d at 1406-07. Appellant's second point is unpersuasive.

3) The claims on appeal define a method comprising "B) leaving the composition in contact with the skin and hair in the infected area until at least most of the ectoparasites, nymphs and eggs have been killed" (claim 1) or "the lice, nymphs and nits have been killed" (claim 45). Claim 28 of the '931 patent defines a method comprising "leaving the composition in contact with the skin and hair for at least 10 minutes until the lice have been killed by suffocation." Claim 1 of the '342 patent defines a method comprising "leaving the composition in contact with the skin and hair until the lice have been killed by suffocation." Appellant's third point is therefore unpersuasive.

4) The generic aspect ("ectoparasites") of the appealed claims is anticipated by the species "lice" in the issued claims, and the requirements for terminal disclaimer were proper in this regard. *See Goodman*, 11 F.3d at 1053. Appellant's fourth point is therefore unpersuasive.

Analysis Involving The Pending '188 Application Claims

Appellant contends that the provisional rejection over the copending application '188 claims should be reversed because the copending claims do not contain these limitations of the claims on appeal:

- 1) the requirement of complete saturation of the hair and skin; and
- 2) topical treatment of ectoparasites, not just lice. (App. Br. 38-39.)

1) The claims on appeal define a method "wherein . . . c) the composition is applied to the infected areas in a quantity sufficient to completely saturate both the hair and the skin in the infected areas." Claim

33 in copending application ‘188 defines a method comprising “A) applying [a composition] to animal skin and hair containing ectoparasites and their eggs.” While the copending application claims do not recite “complete saturation” of hair and skin, we construe the claims to mean what they say: apply the composition to skin and hair. The copending claims require the composition to be left on until most of the ectoparasites have been killed by suffocation. We think that a person of ordinary skill would understand the claim to mean applying enough composition to achieve suffocation, i.e., covering the hair and skin completely. It is permissible to take into account the inferences a person of ordinary skill in the art would employ. *See KSR*, 550 U.S. at 418; *Hoeschele*, 406 F.2d at 1406-07. Appellant’s first point is unpersuasive.

2) Claim 33 in the copending application defines a method “for the topical treatment of ectoparasites and their eggs . . . wherein the ectoparasites are lice and/or mites.” We cannot agree with Appellant’s argument that the copending claims do not contain the “ectoparasites” limitation. Appellant’s second point is therefore unpersuasive.

SUMMARY

We affirm the rejection of claims 45-48, 50-53 and 55-63 under 35 U.S.C. § 102(b) as anticipated by Gans;

We affirm the rejection of claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, 33-36 and 45-63 under 35 U.S.C. § 103(a) as unpatentable over the combined teachings of Lover, Bessette, Cardin and Pearlman;

We affirm the rejection of claims 1, 3-5, 8, 9, 13, 18, 20 and 22-26 on the ground of nonstatutory obviousness-type double patenting over claims 28, 29 and 31-38 of Precopio '931;

We affirm the provisional rejection of claims 1, 3-6, 8, 9, 13, 15, 16, 18, 20, 22-26 and 33 on the ground of nonstatutory obviousness-type double patenting over pending claims 33, 35-38, 44-46, 49-51, 65-67 and 69-81 of Precopio '188; and

We affirm the rejection of claims 1, 3-5, 8, 9, 11, 13, 15, 16, 18 and 20 on the ground of nonstatutory obviousness-type double patenting over claims 1-3, 5-13, 15 and 16 of Precopio '342.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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